

REMARKS

Claims 1-19 are presently pending in the application. Claims 1-19 are rejected. Claims 1, 6 and 19 have been amended. The specification and drawings stand as filed.

Reconsideration of the objections and rejections set forth in the aforementioned Office Action is respectfully requested in view of the following remarks. The basis for the amendments can be found throughout the Specification, Claims and Drawings as originally filed.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lecuyer et al. (USPN 5,843,013) in view of Hakim et al. (USPN 4,596,390).

The Applicant has amended claim 1 to note that the drive means is arranged so as to be activated from the outside of the body of the patient so as to allow the adjustment of the flow rate of the valve in a non-invasive manner. The Applicant respectfully submits that none of the references cited by the Examiner, either solely or in combination with one another, teach or suggest a valve as defined by amended claim 1.

In particular, Lecuyer et al., as admitted by the Examiner, does not disclose a drive means to allow adjustment of the valve in a non-invasive manner. Furthermore, Hakim et al. discloses at many locations throughout the patent that the adjustable valve disclosed therein operates to vary the "popping pressure" of the valve. At Col. 7, lines 32-48, Hakim et al. discloses adjusting the preload of the spring 334 against ball 332 by

using cam 366 to vary the vertical position of free end 364 of central arm 338. The spring load establishes the pressure of the valve. The vertical position of free end 364 may be precisely set at one of 18 different values such that the working pressure of the valve is always at one of 18 possible levels.

In the Background of the Invention portion, Hakim et al. stresses the importance of controlling intraventricular pressure rather than flow (Col. 1, lines 24-26). Hakim et al. further describes operation of the valve at Col. 1, lines 39-47 where it is noted that as the flow rate through the valve increases, the ball moves further away from the seat to provide a larger valve orifice, one that is always large enough that the pressure drop across the orifice never rises much above the popping pressure. Accordingly, the differential pressure across the valves remains nearly constant for any flow rate encountered within the cerebrospinal fluid system.

Based on the teachings of Hakim et al., the Applicant respectfully submits that the Examiner has not provided a *prima facie* case of obviousness. Particularly, one skilled in the art would not be motivated to combine Lecuyer et al. with Hakim et al. due to the express **teaching away** found in Hakim et al. regarding adjusting a popping pressure of the valve but allowing various flow rates through the valve at the set popping pressure. The claimed drive means arranged to allow the adjustment of the flow rate of the valve is not taught or suggested. Accordingly, the Applicant respectfully requests withdrawal of the § 103 rejections to claims 1-5 and 14-18.

Claim 6 has been amended to place the previously dependant claim in independent form. The Applicant respectfully submits that originally filed claim 6 is not obvious in view of the references cited, either solely in or in combination with one

another. Claim 6 recites that the movement means includes a lever mounted on the housing and in abutment on the rod support means where the lever cooperates with cam means of the drive means.

Neither Lecuyer et al. nor Hakim et al. disclose a lever mounted on the housing in combination with the other elements recited in claim 6. On the contrary, Lecuyer et al. discloses no such element as a lever mounted on the housing in abutment on the rod support means where the lever cooperates with cam means of the drive means. Furthermore, as previously indicated, Hakim et al. discloses spring 334 to vary the popping pressure. However, spring 334 is not mounted to the housing of the valve but merely acts to provide a preload against the ball where the preload may be adjusted using the cam.

Additionally, neither of the references cited by the Examiner teach or suggest means of axial movement of the means supporting the rod including a lever mounted on the housing. On the contrary, element 334 of Hakim et al. does not function as a lever to axially move a component such as ball 332 but merely varies the force applied by end 336 of spring 334 on ball 332. As such, the Applicant respectfully submits that the limitations of claim 6 have not been taught or suggested by the references cited by the Examiner and the Applicant respectfully requests withdrawal of the § 103 rejections to claims 6-13.

Regarding claim 19, the Applicant has amended the claim to note that the driver is arranged so as to be activated from outside of a patient and to allow adjustment of the flow rate of the valve in a non-invasive manner.

The Applicant respectfully relies on the arguments and amendments previously set forth relating to adjusting the flow rate of the valve and the teaching away of Hakim et al. Accordingly, the Applicant respectfully requests withdrawal of the § 103 rejection to claim 19.

CONCLUSION

All of the grounds of rejection have been properly traversed, accommodated, or rendered moot. The Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding office action, and as such, the present application is in condition for allowance.

If it is believed that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600. Prompt and favorable consideration of this amendment is respectfully requested.

Respectfully submitted,

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